EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL No. 2804
	:	CASE NO. 17-MD-2804 (DAP)
	:	
	:	

Expert Report of Sheldon T. Bradshaw

May 10, 2019

approval process, and my knowledge of the drug industry. The specific materials that I have relied upon to form my opinions are listed in Exhibit C to this report.

E. Summary of Opinions to Be Expressed

12. I have been retained by counsel for Mallinckrodt LLC and SpecGX LLC ("Mallinckrodt") to render expert opinions regarding the FDA and FDA regulatory matters. In particular, I have been asked to render my expert opinion regarding the drug development process, the FDA new drug approval process, and FDA post-approval oversight and labeling requirements; the standards governing the pharmaceutical industry's advertising and promotion of prescription opioid medicines; and an analysis of Mallinckrodt's advertising and promotion of certain prescription opioid products. Further, I have been asked by counsel to review and provide my opinions regarding the sections of the Expert Report of David Kessler, M.D., that opine on Mallinckrodt's marketing and promotional materials. In so doing, I have formed the following opinions:

- FDA is an independent, science-based organization that conducts thorough reviews of applications to market drug products. It is the gold standard for reviewing and approving drug applications and monitoring approved drugs, and CDER has ample resources to perform these functions.
- FDA has the power and does refuse to approve proposed products that are not shown to be safe and effective. FDA appropriately monitors drugs post approval, and if the Agency determines that the risks associated with use of the drug outweigh its benefits, it is empowered to withdraw approval of the already approved applications.
- The FDA also has authority to approve and actively monitors labeling, advertising, and promotion of medications.
- Dr. Kessler makes a number of critical errors in his analysis of materials he incorrectly categorizes as Mallinckrodt's promotional materials.
- Based on my review of Mallinckrodt's promotional materials regarding Exalgo and Xartemis, I find that Mallinckrodt did comply with the FDA's labeling requirements, its promotional materials did not violate FDA standards and are consistent with the FDA-approved labels.